

Terrestrial Animal Health Standards
Commission Report - March 2008

CHAPTER 2.4.8.

SCRAPIE

Article 2.4.8.1.

The recommendations in this Chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in cattle, sheep and goats. Scrapie is not considered to pose a risk to human health. In the context of this Chapter, 'scrapie' includes all transmissible spongiform encephalopathies in small ruminants except bovine spongiform encephalopathy. That is, the Chapter covers 'classical' scrapie, which is known to be contagious, as well as 'atypical' scrapie which may not be contagious or may be only poorly transmissible.

The recommendations in the present chapter are not intended, or sufficient, to manage the risks associated with the potential presence of the bovine spongiform encephalopathy agent in small ruminants.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from small ruminants, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the small ruminant populations of the *exporting country, zone or compartment*:
 - a) *meat* and *meat products*;
 - b) semen and *in vivo* derived embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
 - c) hides and skins;
 - d) gelatine;
 - e) collagen prepared from hides or skins;
 - f) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
 - g) dicalcium phosphate (with no trace of protein or fat);
 - h) wool or fibre.
2. When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the scrapie risk status of the small ruminant populations of the *exporting country, zone or compartment*.

Article 2.4.8.2.

The scrapie risk status of the sheep and goat populations of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

the outcome of a *risk assessment* identifying potential factors for scrapie occurrence and their historic perspective. In situations where a country *risk assessment* cannot be conducted because of insufficient information, consideration should be given to conducting *risk assessments* on individual *establishments* or *compartments*. The diverse routes of transmission of the agent, including from long-lasting environmental contamination, and long *incubation periods*, may also make compartmentalisation a more practicable option than whole of country assessments.

1. Members should review the *risk assessment* periodically to determine whether the situation has changed.

- a) Release assessment

Release assessment consists of assessing, through consideration of the following, the likelihood that the scrapie agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*:

- i) the presence or absence of the scrapie agent in the indigenous small ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;
- ii) production of *meat-and-bone meal* from the indigenous small ruminant population;
- iii) imported *meat-and-bone meal*;
- iv) imported sheep and goats;
- v) imported animal feed and feed ingredients.

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

- b) Exposure assessment

If the release assessment identifies a risk factor, an exposure assessment should be conducted, consisting of assessing the likelihood of small ruminants being exposed to the scrapie agent, through a consideration of the following:

- i) the eradication measures which are applied following the detection of scrapie in sheep and goat flocks;
- ii) distribution and fate of imported sheep and goats;

- iii) recycling and amplification of the scrapie agent through consumption by small ruminants of *meat-and-bone meal* of ruminant origin, or other feed or feed ingredients contaminated with these;
 - iv) the use of ovine and caprine carcasses (including from fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
 - v) the feeding or not of ruminants with *meat-and-bone meal* derived from ruminants, including measures to prevent cross-contamination of animal feed;
 - vi) the level of surveillance for scrapie conducted on the sheep and goat populations up to that time, the tests used, and the results of that surveillance;
2. the compulsory notification and investigation of all small ruminants showing clinical signs consistent with scrapie;
 3. the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system;
 4. an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of small ruminants to encourage reporting of *cases* showing clinical signs consistent with scrapie.

Article 2.4.8.3.

Negligible scrapie risk

Commodities from the small ruminant populations of a country or *zone* pose a negligible risk of transmitting the scrapie agent if the following conditions are met:

1. a *risk assessment*, as described in point 1 of Article 2.4.8.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
2. the Member has in place a surveillance programme, based on a combination of testing all small ruminants showing clinical signs consistent with scrapie, and appropriate samples of fallen stock, dead-in-transit stock and culled-for-age stock, and capable of detecting *infection* at an annual period prevalence of 0.1% of animals over 18 months of age with 95% confidence and which has failed to detect scrapie for 7 consecutive years;
3. EITHER:
 - a) all *establishments* containing sheep or goats have been accredited as negligible scrapie risk as described in Article 2.4.8.6.;

OR

- b) there has been no *case* of scrapie and
 - i) the criteria in points 2 and 3 of Article 2.4.8.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated through an appropriate level of control and audit that for at least 7 years no *meat-and-bone meal* derived from ruminants has been fed to ruminants;

OR

- c) if there has been a *case* of scrapie, every *case* was born more than 9 years ago; and
 - i) the criteria in points 2 and 3 of Article 2.4.8.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated through an appropriate level of control and audit that for at least 7 years no *meat-and-bone meal* derived from ruminants has been fed to ruminants;
 - iii) and
 - in the case of classical scrapie, all *cases* have been culled, as well as all sheep (except rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ) and all goats, or
 - in the case of atypical scrapie, all *cases* have been culled, as well as all sheep carrying the AF¹⁴¹RQ allele;
4. introductions of sheep and goats for breeding are made only from a country, *zone* or *compartment* of negligible scrapie risk or an *establishment* or *compartment* free from scrapie as described in Article 2.4.8.6.

Article 2.4.8.4.

Controlled scrapie risk

Commodities from the small ruminant populations of a country, *zone* or *compartment* pose a controlled risk of transmitting the scrapie agent if the following conditions are met:

1. a *risk assessment*, as described in point 1 of Article 2.4.8.2., has been conducted in order to identify the historical and existing risk factors and the Member has demonstrated that appropriate measures are being taken to manage all identified risks;
2. the Member has in place a surveillance programme, based on a combination of testing all small ruminants showing clinical signs consistent with scrapie, and appropriate samples of fallen stock, dead-in-transit stock and culled-for-age stock, and capable of detecting *infection* at an annual period prevalence of 0.1% of animals over 18 months of age with 95% confidence;

3. EITHER:

- a) there has been no *case* of scrapie, the criteria in points 2 to 4 of Article 2.4.8.2. are complied with and it can be demonstrated through an appropriate level of control and audit that no *meat-and-bone meal* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:
 - i) the criteria in points 2 and 3 of Article 2.4.8.2. have not been complied with for 5 years;
 - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* derived from ruminants to ruminants have been in place for 5 years;

OR

- b) there has been a *case* of scrapie, the criteria in points 2 and 3 of Article 2.4.8.2. are complied with, and it can be demonstrated that controls over the feeding of *meat-and-bone meal* derived from ruminants to ruminants have been in place for 5 years and;
 - i) in the case of classical scrapie, all *cases* have been culled, as well as all sheep except rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ, and all goats, or
 - ii) in the case of atypical scrapie, all *cases* have been culled, as well as all sheep carrying the AF¹⁴¹RQ allele.

4. EITHER:

- a) introductions of sheep and goats for breeding are made only from a country, *zone* or *compartment* of negligible scrapie risk or an *establishment* or *compartment* free from scrapie as described in Article 2.4.8.6., or

OR

- b) introductions of sheep for breeding are restricted to rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ.

Article 2.4.8.5.

Undetermined scrapie risk

The small ruminant populations of a country, *zone* or *compartment* poses an undetermined scrapie risk if it cannot be demonstrated that it meets the requirements of another category.

Article 2.4.8.6.

Negligible scrapie risk establishment or compartment

An *establishment* or *compartment* can be considered eligible for accreditation as negligible scrapie risk if:

1. the *establishment* or *compartment* is situated within a country that meets the requirements for negligible scrapie risk according to Article 2.4.8.3., or
2. the *establishment* or *compartment* is situated within a country that meets the requirements for controlled scrapie risk according to Article 2.4.8.4., and
 - a) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;
 - b) in the *establishment* the following conditions have been complied with for at least 7 years:
 - i) sheep and goats should be permanently identified and records maintained, to enable trace back to their *establishment* of birth and to any other *establishment* on which they may have resided since birth;
 - ii) records of movements of sheep and goats in and out of the *establishment* or *compartment* are established and maintained;
 - c) introductions of animals are allowed only from *establishments* of an equal or higher stage in the process of accreditation; however, rams of the ARR/ARR genotype may also be introduced;
 - d) an *official veterinarian* inspects sheep and goats in the *establishment* or *compartment* and audits the records at least once a year;
 - e) no *case* of scrapie has been reported;
 - f) sheep and goats of the establishment or compartment should have no direct or indirect contact with sheep or goats from establishments of a lower status;
 - g) all culled animals over 18 months of age are inspected by an *official veterinarian*, and all animals exhibiting neurological or wasting signs are tested in a *laboratory* for scrapie; all animals over 18 months of age that have died or have been killed for reasons other than routine slaughter should also be tested (including fallen stock, dead-in-transit stock and animals sent for emergency slaughter);
 - h) intermediate stages of accreditation may be considered where compliance for the full time frames prescribed is not yet possible, but where a level of control sufficient to reduce the risk to other small ruminants is shown to in place;
3. if there has been a *case* of scrapie on the *establishment*:
 - a) in the case of classical scrapie, all *cases* have been culled and destroyed, as well as all sheep (except rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ) and all goats, or
 - b) in the case of atypical scrapie, all *cases* have been culled and destroyed, as well as all sheep carrying the AF¹⁴¹RQ allele.

Article 2.4.8.7.

When importing from a country, *zone* or *compartment* posing a negligible scrapie risk, *Veterinary Authorities* should require:

for commodities from sheep and goats not listed in Article 2.4.8.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.8.3.

Article 2.4.8.8.

When importing from a country, *zone* or *compartment* posing a negligible scrapie risk, *Veterinary Authorities* should require:

for sheep and goats for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals come from a country, *zone* or *compartment* which complies with the conditions in Article 2.4.8.3.

Article 2.4.8.9.

When importing from a country, *zone* or *compartment* posing a negligible scrapie risk, but in which there has been an indigenous case, *Veterinary Authorities* should require:

for sheep and goats for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

1. are identified by a permanent identification system in such a way as to demonstrate that, regardless of genotype, they have never been present in the same flock as a case;
2. were born after the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.

Article 2.4.8.10.

When importing from a country, *zone* or *compartment* not complying with the conditions in Article 2.4.8.3., *Veterinary Authorities* should require:

for sheep and goats for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

1. come from an *establishment* or *compartment* posing a negligible scrapie risk as described in Article 2.4.8.6.
2. are identified by a permanent identification system in such a way as to demonstrate that, regardless of genotype, they have never been present in the same flock as a case;
3. were born after the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.

Article 2.4.8.11.

When importing sheep and goats for immediate slaughter, *Veterinary Authorities* should require: the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
 - a) the *disease* is compulsorily notifiable;
 - b) affected sheep and goats are slaughtered and completely destroyed;
2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 2.4.8.12.

Veterinary Authorities of importing countries should require:

for ovine and caprine materials destined for the preparation of biologicals intended for administration to small ruminants

the presentation of an *international veterinary certificate* attesting that:

1. the products originate from sheep or goats born and raised in a country, *zone* or *compartment* of negligible scrapie risk or an *establishment* or *compartment* free from scrapie as described in Article 2.4.8.6.; or
2. the products originate from a country or *zone* posing a controlled scrapie risk, are derived from sheep and goats which passed ante- and post-mortem inspections, and have not been prepared using the tissues listed in Article 2.4.8.15.

Article 2.4.8.13.

1. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* defined in Article 2.4.8.3., but in which there has been an indigenous *case* of scrapie, should not be traded if such products were derived from animals born before the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.
2. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* not complying with the conditions referred to in Article 2.4.8.3 should not be traded between countries.

Article 2.4.8.14.

1. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* defined in Article 2.4.8.3., but in which there has been an indigenous *case* of scrapie, should not be traded if such products were derived from animals born before the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.

2. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* not complying with the conditions referred to in Article 2.4.8.3 should be certified as being derived from sheep and goats which passed ante- and post-mortem inspections, and was not been prepared using the tissues listed in Article 2.4.8.15.

Article 2.4.8.15.

1. From small ruminants of any age originating from a country, *zone* or *compartment* not complying with the conditions referred to in Article 2.4.8.3., the following *commodities*, and any *commodity* contaminated by them, should not be traded for the preparation of feed, fertilisers, or veterinary pharmaceuticals including biologicals: spleen and ileum. Protein products intended for animal use, feed, fertilisers or veterinary pharmaceuticals prepared using these *commodities* (unless covered by other Articles in this Chapter) should also not be traded.
2. From small ruminants that were at the time of *slaughter* over 12 months of age or which have a permanent incisor erupted through the gum originating from a country, *zone* or *compartment* not complying with the conditions referred to in Article 2.4.8.3., the following *commodities*, and any *commodity* contaminated by them, should not be traded for the preparation of feed, fertilisers, or veterinary pharmaceuticals including biologicals: skull, brain, eyes, spinal cord. Protein products intended for animal use, feed, fertilisers or veterinary pharmaceuticals prepared using these *commodities* (unless covered by other Articles in this Chapter) should also not be traded.